PHARMABIZ.com
india's most comprehensive pharma portal

Prof Baker too finds fault with Mashelkar's revised report after Correa's objections

Thursday, October 29, 2009 08:00 IST
Ramesh Shankar, Mumbai

Close on the heels of international patent expert professor Carlos Correa's criticism of the revised Mashelkar Committee report, another international patent expert professor Brook K Baker has lambasted the Mashelkar Committee report stating that the revised version underestimates India's right to define patentability.

For the second time, the Mashelkar Committee has misinterpreted India's flexibility under international law to limit patents of pharmaceutical products to new chemical entities, or new medical entity involving one or more inventive steps (NCEs), professor Baker said.

Although the Mashelkar report slightly modified and extended its analysis, it has made three fundamental mistakes: it still incorrectly analyses India's flexibilities under TRIPS to define pro-health standards of patentability; it fails to analyse key TRIPS-minimum patent standards, especially novelty and inventive step; and it incorrectly concludes that a NCE-only standard of patentability for NCEs would constitute discrimination against a field of technology and in doing so misinterprets and misapplies the expert analysis of Professor Carlos Correa, an internationally renowned IP specialist.

The Mashelkar II Report provides only limited analysis of the most relevant provision of the TRIPS Agreement, Article 27. Although it refers the patentability standards of newness (novelty), inventive step, and industrial applicability, it undertakes no real analysis of the core minimums of these imprecise terms.

In its first fundamental error, the Report mistakenly implies that the definition of invention (newness, inventive step, and industrial capacity) contained in Article 27.1 has any particular and definite meaning within the WTO TRIPS Agreement and that India lacks interpretive flexibility to give pro- health meanings to those terms. In particular, the Report ignores (does not even address) the flexibility that countries like India have under Article 1.1 of the TRIPS Agreement, which states that 'Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice'. (Emphasis added.) Likewise, it ignores interpretive flexibilities arising from Articles 7 & 8, from the Doha Declaration, and from India's right-to-health human rights commitments, professor Baker said .

Ignoring the interpretive flexibility granted by Article 1.1, the interpretive guidance provided by Articles 7 and 8 and by the Doha Declaration, and human rights mandates imbedded in India's legal regime, the Report instead focuses on the language of Article 1 that requires what it calls 'compliance with the provisions of the Agreement.' (5.9.) It is here that the Mashelkar II Report makes its second fundamental error – it assumes, without prior proof or discussion that 'limiting pharmaceutical patents to new chemical

entities only, and excluding new forms of crystals, polymorphs, etc, if they satisfy the criteria of patentability, is not consistent with TRIPS Agreement.' (Emphasis added.) Having never discussed the meaning of 'new', 'inventive step' or 'industrial application' as minimally articulated in the TRIPS Agreement, the Mashelkar Committee nonetheless immediately assumes that 'new forms' of existing chemical entities might automatically satisfy all the criteria of patentability. However, this is precisely the question the Committee was asked to address, which it never does, professor Baker said.

On this issue, the Committee has failed to analyze the serious question of whether non-NCEs might fail properly articulated, TRIPS-minimum standards for newness and inventive step. Many of what the Committee calls 'new forms' of existing chemical entities may actually be part of the prior art or are disclosed within the patent grant of the original new chemical entity. However, even when this is not the case, non-NCEs will almost always fail the inventive step test. Once, the NCE is invented, it is now common practice – the routine discovery-oriented drudgery of applied chemistry – for research chemists to look for salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of [a] known substance. The resulting routine discoveries – not inventions – are the obvious byproducts of elbow grease, not inspiration, and use discovery and production methods well known in the industry. According to this same analysis, discovery of new uses of known chemical entities also lacks a true inventive step.

In its third fundamental error, Mashelkar Report II claims that limiting pharmaceutical patents to NCEs would constitute prohibited discrimination against a field of technology and thus be prohibited by Article 27. To the contrary, the TRIPS Agreement clearly permits differentiation between fields of technology, even though it does not permit out-and-out discriminatory exclusion of pharmaceutical patents as a class nor discrimination against other discrete fields of technology such as pollution control devises.

In an attempt to justify its third fundamental error, the Mashelkar II Report mischaracterized and misapplies the expert opinion of Professor Carlos Correa. Although it correctly cites that Professor Correa had previously opined that Article 27.1 does not permit the exclusion from patentability of medicines in general as a field of technology nor, arguably, specific sub-groups thereof [for example, WHO essential medicines] (5.8), it then over-extends that analysis to conclude that non-NCEs are such a 'field of technology' and that it would be improper to exclude what it calls new forms of crystals, polymorphs, etc. from patent protection (5.9), professor Baker said.